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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,096	02/01/2001	Dan Nilsson	54337.000009	6906

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HUNTON & WILLIAMS
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 05/05/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/720,096

Applicant(s)

NILSSON ET AL.

Examiner

David J. Steadman

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 April 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: see attachment.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1-17 and 24-32.

Claim(s) withdrawn from consideration: 18-23.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____.

ADVISORY ACTION

[1] Claims 1-32 are pending in the application.

[2] Claims 18-23 remain withdrawn from consideration.

[3] Claims 1-17 and 24-32 stand finally rejected.

[4] The request for reconsideration in the after final amendment of Paper No. 18, filed 04/08/03, is acknowledged. The amendment would appear to overcome previously applied objections and/or rejections. However, the amendment of Paper No. 18 does not place the claims in condition for allowance because the amendment would require further consideration of the claims as at least one new rejection would be required (see item 5 below). See MPEP 714.13 regarding non-entry of after final amendments.

[5] It is noted that entry of the amendment would require at least one new rejection. Specifically, a new rejection under 35 USC 112, second paragraph, would be required in the recitation of "the substrate material" in claim 16. There is no antecedent basis for the term "the substrate material" in the claim.

[6] The objection to claims 24 and 25 is maintained for the reasons of record and the reasons set forth below. Applicant argues (page 7 of Paper No. 18) the objection is overcome by amendment. However, in view of the non-entry of the amendment, the objection is maintained for the reasons of record. It is noted that the amendment would appear to overcome the objection.

[7] The rejection of claims 1-17, 26, and 27 under 35 USC 112, second paragraph, is maintained for the reasons of record and the reasons set forth below. Applicant argues (page 7 of Paper No. 18) the rejection is overcome by amendment. However, in view of the non-entry of the amendment, the rejections are maintained for the reasons of record. It is noted that the amendment would appear to overcome the rejection.

[8] The written description rejection of claims 1-3, 6-19, 21-27, and 30-32 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons set forth below. Applicant argues (beginning at page 7 of Paper No. 18) the rejection is overcome by amendment. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would not appear to overcome the rejection. Even if the amendment were entered, the

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specification fails to provide adequate written description for the genus of recited bacterial strains or conditional mutants. The claims recite a broad genus of modified bacterial strains and conditional mutants that have not been adequately described in the specification. The disclosed species of modified bacterial strains, i.e., a purine or thymidine *L. lactis* auxotrophic mutant, fail to provide a representative number of species sufficient to represent the entire genus of recited bacterial strains. As such, a skilled artisan would recognize that applicant was not in possession of the recited genus of bacterial strains or conditional mutants at the time of the invention.

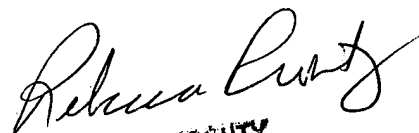
[9] The scope of enablement rejection of claims 1-17 and 24-32 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons set forth below. Applicant argues (beginning at page 8 of Paper No. 18) the specification provides a teaching that enables a skilled artisan to make the entire scope of the claimed invention. Applicant argues that the amendment to limit the substrate material to milk, along with the teachings provided in the specification (properties of a bacterial culture, concentration of a bacterial strain, disclosure of different types of non-proliferating cells, specific embodiments of the invention) provide an enabling disclosure. Regarding the development of an auxotrophic bacterial strain, applicant argues the invention is not directed to the development of auxotrophic strains, but is directed to the use of auxotrophic strains according to the methods of the invention. Applicant argues that working examples of the claimed invention have been provided in the specification. Applicant argues the declaration of Dan Nilsson asserted that making the entire scope of the claimed invention would not require undue experimentation. However, in view of the non-entry of the amendment, the rejection is maintained for the reasons of record. It is noted that the amendment would not appear to overcome the rejection. Even if the amendment were entered, it is the examiner's position that undue experimentation would be required to make the entire scope of the claimed invention. The teachings provided by the specification and the disclosure of a purine or thymidine *L. lactis* auxotrophic mutant as working examples fails to sufficiently enable a skilled artisan to make the entire scope of recited bacterial strains used in the claimed methods. While the substrate material would be limited to milk, the specification provides insufficient guidance for those modifications that may result in a bacterial

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strain having the desired characteristics. While screening techniques for isolating auxotrophic bacterial strains and conditional mutants are known in the art, it is not routine to screen for all modifications to any bacterial strain that result in the desired bacteria as broadly encompassed by the claims. Such experimentation would not be considered routine experimentation. As such, undue experimentation would be required to make the entire scope of the claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652


REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1800
1600